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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2004D–0499]

Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) Sec. 400.210 entitled "Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs." The CPG describes the agency's intent to exercise enforcement discretion, until December 31, 2007, concerning certain regulatory requirements to facilitate the performance of feasibility studies and pilot programs involving Radiofrequency Identification (RFID) tags for drugs. The goal of the CPG is to allow industry to gain experience with the use of RFID technology to ensure the long-term safety and integrity of the U.S. drug supply.

DATES: You may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit

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electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Paul Rudolf, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

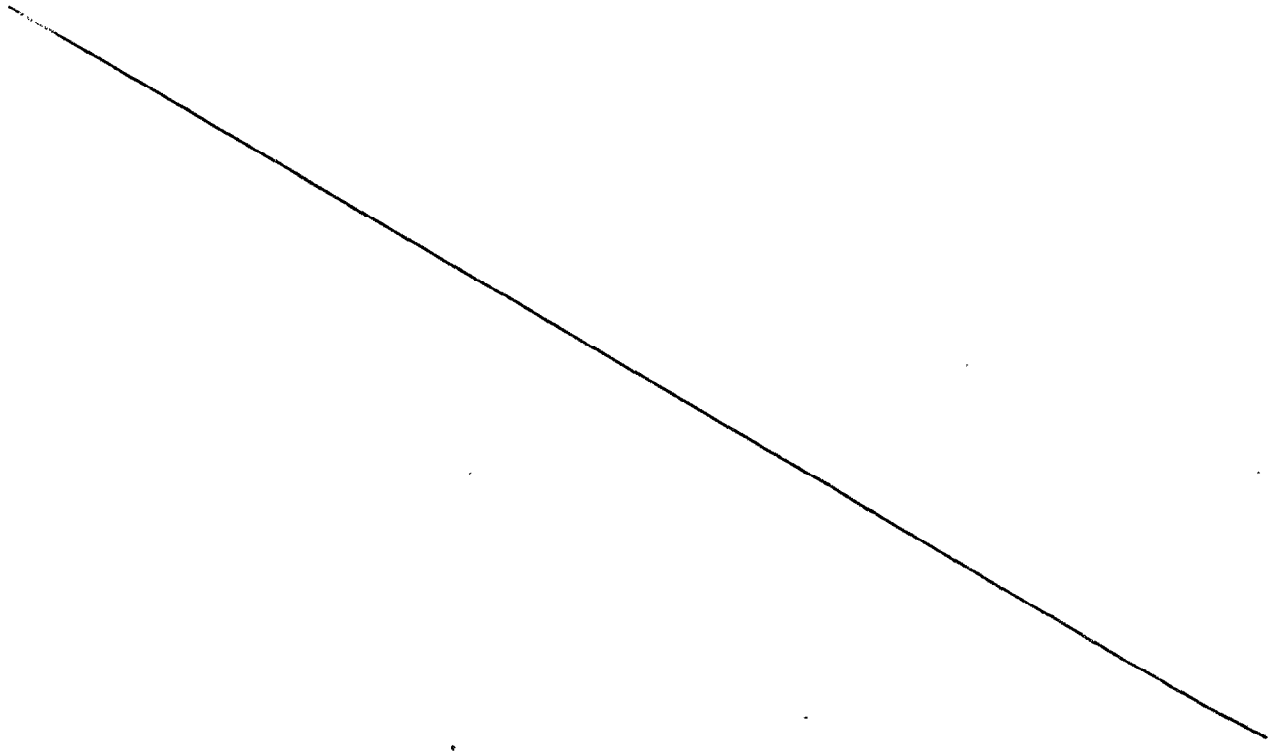
On February 18, 2004, FDA published a report entitled "Combating Counterfeit Drugs" which is available on the FDA Web site at *http://www.fda.gov/oc/initiatives/counterfeit.* In that report the agency identified RFID technology as the cornerstone in the fight against counterfeit drugs and announced our intention to facilitate the adoption of RFID technology by participants in the pharmaceutical supply chain. We also stated that widespread adoption of RFID technology was feasible by 2007.

Recently, FDA has received inquiries focusing on whether certain regulatory requirements, including those related to labeling, electronic records, and product quality, apply to pharmaceutical manufacturers, repackagers, relabelers, distributors, retailers, or others who participate in feasibility studies and pilot programs (collectively "a study" or "studies") using RFID tags for drugs. This CPG describes how we intend to exercise our enforcement discretion regarding such studies. The exercise of such enforcement discretion expires on December 31, 2007. The goal of this CPG is to facilitate the performance of RFID studies and allow industry to gain experience with the use of RFID.

FDA is issuing this document as a level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The new CPG Sec. 400.210 is being implemented immediately without prior public comment under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate, but comments are welcome at any time. The agency also thinks that use of RFID technology is critical to ensuring the long-term safety and integrity of the U.S. drug supply and immediate guidance is needed to facilitate studies of RFID.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.fda.gov/ora* under "Compliance Reference."

Dated: 11/10/04
November 10, 2004.

John Taylor,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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